



NOV 19 2003

Thomas Hoxie  
Novartis Pharmaceuticals Corporation  
Patent and Trademark Dept.  
564 Morris Ave.  
Summit, NJ 07901-1027

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,521,184

#19

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,521,184, which claims the human drug product Gleevec® (imatinib mesylate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 586 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 586 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of November 18, 2002 (67 Fed. Reg. 69533). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,025) + 73 \\ &= 586 \text{ days}\end{aligned}$$

Since the regulatory review period began May 10, 1998, after the patent issue date (May 28, 1996), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	5,521,184
Granted	:	May 28, 1996
Original Expiration Date	:	May 28, 2013
Applicant	:	Jürg Zimmerman
Owner of Record	:	NOVARTIS CORPORATION
Title	:	Pyrimidine Derivatives and Processes for the Preparation Thereof

Classification : 514/252  
Product Trade Name : Gleevec® (imatinib mesylate)  
Term Extended : 586 days  
Expiration Date of Extension : January 4, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents  
Box Patent Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

By FAX: (703) 872-9411

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Ferriter

Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: David T. Read      RE: Gleevec® (imatinib mesylate)  
Acting Director Health Assessment Policy Staff, CDER      FDA Docket No.: 02E-0024  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

## Patent Assignment Abstract of Title

**Total Assignments: 3**

**Application #:** 08234889 **Filing Dt:** 04/28/1994 **Patent #:** 5521184 **Issue Dt:** 05/28/1996  
**PCT #:** NONE **Publication #:** NONE **Pub Dt:**

**Inventor:** JURG ZIMMERMANN

**Title:** PYRIMIDINE DERIVATIVES AND PROCESSES FOR THE PREPARATION THEREOF

**Assignment: 1**

**Reel/Frame:** 007767/0596 **Received:** 01/30/1996 **Recorded:** 01/02/1996 **Mailed:** 04/22/1996 **Pages:** 2

**Conveyance:** ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

**Assignor:** ZIMMERMANN, JURG

**Exec Dt:** 04/08/1994

**Assignee:** CIBA-GEIGY CORPORATION

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**Assignment: 2**

**Reel/Frame:** 011979/0294 **Received:** 07/19/2001 **Recorded:** 07/03/2001 **Mailed:** 09/21/2001 **Pages:** 4

**Conveyance:** CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).

**Assignor:** CIBA-GEIGY CORPORATION

**Exec Dt:** 12/31/1996

**Assignee:** NOVARTIS CORPORATION

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**Assignment: 3**

**Reel/Frame:** 011089/0648 **Received:** 10/11/2000 **Recorded:** 08/22/2000 **Mailed:** 11/14/2000 **Pages:** 5

**Conveyance:** CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).

**Assignor:** CIBA-GEIGY CORPORATION

**Exec Dt:** 06/12/1997

**Assignee:** NOVARTIS CORPORATION

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Search Results as of: 1/7/2004 2:11:39 P.M.

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If you have any comments or questions concerning the data displayed, contact OPR / Assignments at 703-308-9723  
Web interface last modified: Oct. 5, 2002